



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re the Application of:) Group Art Unit: 1648
DUKE et al.) Examiner: Lucas, Z.
Serial No.: 09/991,363)
Filed: November 15, 2001) RESPONSE TO SECOND
Atty. File No.: 3923-3) RESTRICTION REQUIREMENT
For: "YEAST-DENDRITIC CELL)
VACCINES AND USES THEREOF") EXPRESS MAIL: EV332358296US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This response is filed in response to the Restriction Requirement having a mailing date of May 20, 2003. Enclosed herewith is a Request for a three-month extension of time and the requisite fee, to extend the time for response from June 20, 2003 to September 20, 2003. No additional fees are believed to be due in connection with this response, but if fees are due, please debit Deposit Account No. 19-1970.

The Examiner has restricted the present application into four groups of claims, as follows: Group I (Claims 1-15) directed to therapeutic compositions; Group II (Claims 16-22) directed to a method of making compositions; Group III (Claims 23-25) directed to a method of eliciting an immune response; and Group IV (Claims 26-28) directed to methods of eliciting an immune response. Applicants confirm their prior election with traverse to prosecute Group I (Claims 1-15).

Applicants again traverse the restriction between Group I and Groups II and III. The Patent Office may require restriction if two or more "independent and distinct" inventions are claimed in one application. However, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P. Section 803. With regard to Group I and either of Groups II or III, Applicants submit that the method of Group II is a method to produce the

composition of Group I, and the method of Group III requires the use of the composition of Group I. Therefore, Applicants submit that a thorough search for the subject matter of Group I will be sufficient to examine the claims of Group II or Group III. In any event, if the elected claims of Group I are found allowable, Applicants reserve their right to amend the claims of Groups II and/or III to be commensurate in scope with the product claims of Group I, and to request that such amended method claims that depend from or otherwise include all the limitations of the allowable product be rejoined and examined for patentability. In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996); In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995).

Additional Restriction Requirement

The Examiner has also required the following additional restrictions for each of Groups I-IV, as follows.

First, the Examiner has made a restriction among the following types of therapeutic compositions (directed to Claims 4, 6 and 8, respectively):

- A) The yeast vehicle is loaded intracellularly with antigen;
- B) The antigen is covalently or non-covalently attached to the yeast vehicle; or
- C) The yeast and antigen are associated by mixing.

Applicants provisionally elect, with traverse, to prosecute **Subgroup C (the yeast and antigen are associated by mixing)**. Applicants traverse the restriction between Groups A, B and C. The Patent Office may require restriction if two or more "independent and distinct" inventions are claimed in one application. However, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P. Section 803. Applicants submit that a thorough search for Group A should also include the subject matter of Groups B and C. More specifically, Claim 1, which is the independent claim, is not limited by the method by which the yeast and antigen are/were associated with one another. Claims 4, 6 and 8 represent various embodiments by which one can produce the composition of Claim 1. Therefore, Claim 1 is, at a minimum, a linking claim. The Examiner states that each of subgroups A-C are compositions with different structures and have different modes of operation. However, it is submitted that by any of these methods of associating the yeast and the antigen, one still arrives at the composition of Claim

1, which comprises the dendritic cell that has been loaded intracellularly with the yeast vehicle and antigen, such composition having one mode of action. If the Examiner performs a thorough search for Claim 1, then such search should be sufficient to examine each of Groups A-C. As such, in the present case, the subject matter of these Groups cited by the Examiner is sufficiently small and is so closely related as to be capable of examination together. The restriction requirements in this case only serve to increase the prosecution expense to the Applicants and to the Patent and Trademark Office. Applicants respectfully request that the Examiner withdraw the restriction requirements.

Second, the Examiner has made a restriction among the following eight types of antigens with regard to Claim 9:

- i) viral antigen
- ii) mammalian cell surface antigen
- iii) bacterial antigen
- iv) fungal antigen
- v) protozoan antigen
- vi) helminth antigen
- vii) ectoparasite antigen
- viii) cancer antigen.

Applicants provisionally elect, with traverse, to prosecute Subgroup viii) cancer antigen. Applicants traverse the restriction among the antigen types. Claim 9 lists preferred types of antigens that can be used in the present invention, but it is not intended to limit the present invention, particularly since there are other antigens other than those listed in the preferred embodiment, which could be used in a composition of the invention. Claim 1 is not limited to a particular type of antigen and therefore is at a minimum, a linking claim. The Examiner should be able to perform a thorough search for the invention as set forth in Claim 1 that is sufficient to examine all of the groups together. The Examiner asserts that the use of different antigens results in compositions having different modes of operation, different function, or different effects. However, Applicants assert that the composition, regardless of the antigen, operates, functions or results in the effect of eliciting an immune response against the antigen in an animal. The general composition, regardless of the antigen, more specifically operates or functions via the activation of dendritic cells by the yeast-

antigen complexes to produce IL-12 and to prime MHC class I- and class II-restricted, antigen-specific T cell responses. Thus, regardless of the antigen used, the general mode of operation and effect are the same. The fact that different antigens are used to elicit immune responses for a particular vaccine strategy, or to treat a specific disease or condition is a level of detail that Applicants believe is unfairly used in this application to restrict the invention unnecessarily. Again, the restriction requirements in this case only serve to increase the prosecution expense to the Applicants and to the Patent and Trademark Office, and Applicants respectfully request that this restriction be withdrawn.

Third, since Applicants have argued above for the rejoinder of Group II with Group I, then the Examiner has required a further restriction among:

- IIA transfecting the yeast vehicle with a nucleic acid expressing the antigen;
- IIB loading the yeast vehicle with the antigen;
- IIC mixing the yeast with the antigen; or
- IID physically attaching the antigen to the yeast vehicle.

Applicants provisionally elect, with traverse, **Group IIA (transfecting the yeast vehicle with a nucleic acid expressing the antigen)**. If Groups II is rejoined with Group I, Applicants traverse the restriction between Groups IIA-IID. The actual technique that is used to load the yeast vehicle with the antigen and thus form the yeast vehicle-antigen complex according to the first step of Claim 16 does not change the fact that each technique results in the formation of a yeast vehicle-antigen complex that can be then loaded into the dendritic cell to complete the composition. Each technique is a useful technique to achieve the step of forming the complex, and indeed, Applicants do not intend to limit the invention to one technique. To limit a method in an invention to specific laboratory techniques by which the method can be achieved is an unnecessary and unduly limiting burden to place on Applicants. It is submitted that a thorough search for the subject matter of the generic or linking claim, Claim 16, should be sufficient to examine each of Groups IIA-IID together. This restriction requirement only serves to increase the prosecution expense to the Applicants and to the Patent and Trademark Office, and Applicants respectfully request that this restriction be withdrawn.

Species Elections

The Examiner has also required several species elections as follows.

First, the Examiner has required an election of one of the 5 yeast vehicle types recited in Claim 15. Applicants provisionally elect, with traverse, the species of (a) whole yeast cells. Claims 1-15 of the elected group read on this species. Applicants submit that no reason was provided for this species election and that a thorough search for the generic claim will be sufficient to examine all species.

Second, the Examiner has required an election of one of the 9 different species of yeast recited in Claim 14. Applicants provisionally elect, with traverse, the species of (1) Saccharomyces. Claims 1-15 of the elected group read on this species. The Examiner has not provided any reasons why one species of yeast would be expected to be different from another in the claimed composition, and Applicants submit that such a limitation is unnecessary and will not facilitate the Examiner's search of the invention.

The third species election does not apply because Applicants did not elect a viral antigen. However, if the antigen groups are rejoined as requested, then Applicants elect, with traverse, the species of i-(a) HIV-1 gag. Claims 1-15 of the elected group read on this species. With regard to this species election, Applicants submit that this election is clearly solely an effort to facilitate the search on the part of the Examiner. It is not believed that restriction and species election practice is generally intended to pull apart each and every dependent embodiment of an invention, which only limits the ability of an Applicant to obtain the proper protection for an invention and which clearly increases the burden on both applicants and the Patent Office. It is submitted that examination of the generic claim is sufficient to examine all claims.

Fourth, for Group II, if rejoined with Group I, and if the vehicle preparations of IIA-IID are rejoined, then applicants provisionally elect, with traverse, from the methods of loading the dendritic cell with the yeast in Claim 22, the species of III(e) phagocytosis. Claims 16-22 read on this election.

Fifth, for Group II, if rejoined with Group I, then applicants provisionally elect, with traverse, from the methods of loading yeast with the antigen in Claim 18, the species of III-(d) eletroporation. Claims 16, 18, and 22 read on this election.

With regard to both of the fourth and fifth species above, it is submitted that a search of the generic claim is sufficient to allow the Examiner to fully examine the methods, without a limitation to the techniques by which the method steps are performed. Limitation of the claims to laboratory techniques would be an undue limitation of the Applicants' invention and severely increases the expense and burden on both Applicants and the Patent Office.

With general regard to all of the Examiner's species election requirements, Applicants note that such requirements are primarily, if not solely, intended to facilitate a search by the Examiner. Applicants note that the Examiner is obligated to examine the generic claims and submit that the scope of the claims of the present invention is not limited to the elected species.

In view of the foregoing remarks, Applicants respectfully request that the Examiner withdraw the Restriction Requirements and species elections.

Respectfully submitted,

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